2587 '60 107 -6 October 2, 2000

Office of Special Nutritionals (HFS-450) 2 5 8 7 Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

Re: Maginex TM DS

Ladies and Gentlemen:

This letter notifies the Food and Drug Administration that within the past 30 days our company has begun to market Maginex DS, a magnesium dietary supplement, with the following statements of nutritional support included on the label and in labeling the product:

Clinical research links magnesium with the proper function of:

- Heart and cardiovascular system
- Muscle and bone structure
- Metabolism of naturally produced substances within the body, such as glucose\*

Americans with certain heart and circulatory conditions are at a greater risk for magnesium depletion. The use of particular diuretics, consumption of alcohol and strenuous activity may further deplete the body of magnesium. Symptoms of magnesium depletion may include occasional leg cramping, restlessness and headaches.\*

The dietary ingredient of the product that is subject to the above statement is:

Magnesium

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement is truthful and not misleading.

Very truly yours,

Geist Pharmaceuticals, LLC

Gennifer Ponski Chief Executive

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